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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number: 09143-017001
CERTIFICATE OF MAILING BY EFS-WEB FILING I hereby certify that this paper was filed with the United States Patent and Trademark Office using the EFS –WEB system on this date: June 18, 2007	Application Number 09/800,195	Filed March 6, 2001
	First Named Inventor Suk Cho et al.	
	Art Unit 1618	Examiner Simon Oh

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a Notice of Appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

☒ attorney or agent of record
(Reg. No. 42,782)

☐ attorney or agent acting under 37 CFR 1.34.
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June 18, 2007
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NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below'.

☒ Total of 1 forms are submitted.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Suk Cho et al.	Art Unit	: 1618
Serial No.	: 09/800,195	Examiner	: Simon Oh
Filed	: March 6, 2001	Conf. No.	: 3370
Title	: DIETARY SUPPLEMENT COMPOSITIONS		

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicants submit this request pursuant to the Pre-Appeal Conference Pilot Program described in the United States Patent and Trademark Office OG Notice "New Pre-Appeal Brief Conference Pilot Program," dated 12 July 2005. This request is filed together with a Notice of Appeal and a Petition for Extension of Time (2 months). Review of the matters identified below by a panel of examiners is requested because the rejections of record clearly exhibit legal and/or factual deficiencies. Applicants reserve all rights to address the matters herein and any additional matters on appeal in a subsequent appeal brief.

Claims 1-24, 33 and 34 are pending. The Office rejected claims 1-24, 33 and 34 under 35 U.S.C. § 103(a) as being unpatentable over Perkes (WO 99/07400) ("Perkes") in view of Shrikhande *et al.* (U.S. Pat. No. 6,544,581) ("Shrikhande"). Applicants respectfully traverse these rejections.

In particular, Applicants specifically request the panel to review the issues below.

Legal Error #1: The Office Misapplied the Obviousness Standard

Claims 1-24, 33 and 34 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Perkes (WO 99/07400) ("Perkes") in view of Shrikhande *et al.* (U.S. Pat. No. 6,544,581) ("Shrikhande"). As the Office correctly stated, the Supreme Court recently clarified that for an invention to be obvious under § 103 requires consideration of the factors set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), including an analysis of the scope and content of the prior art and the differences between the claimed subject matter and the prior art. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. ___ (2007), 2007 WL 1237837 (hereinafter "KSR").

In applying KSR, the Office stated that Perkes disclosed compositions similar to the ones presently claimed, but did not explicitly mention the use of Muscat grape seed extracts. To fill this difference in content between the prior art and the present claims, the Office stated that Shrikhande disclosed the use of Muscat grape seeds in the preparation of a nutritional composition, a disclosure which the Office alleged that one having ordinary skill in the art would view as useful guidance in the choice of a grape seed extract for use in the Perkes compositions.

Applicants respectfully disagree for the prior reasons of record. Moreover, Applicants assert that the holding in KSR did *not* change binding Federal Circuit precedent that unexpected results can be used to rebut a *prima facie* finding of obviousness. "Rebuttal [of a case of prima facie obviousness based on structural similarity] can consist of a comparison of test data showing that the claimed compositions possess unexpectedly improved properties or properties that the prior art does not have." *See In re Dillon*, 919 F.2d 688 (Fed. Cir. 1990). Furthermore, "a claimed article must show superior results compared with the result achieved by the *closest prior art*." *See In re De Blauwe*, 736 F.2d 699 (Fed. Cir. 1984) (emphasis added). While is no way conceding that the Office has established a *prima facie* case of obviousness, Applicants respectfully assert that the prior evidence of record as to unexpected results clearly rebuts any alleged *prima facie* case of obviousness.

In an Office Action dated February 3, 2003, in rejecting the claims under 35 U.S.C. § 103 over the Perkes reference and the Gaynor *et al.* reference (U.S. Pat. No. 5,904,924, hereinafter "Gaynor"), the Office stated that "applicant has not provided comparisons related to the results obtained by using that particularly claimed variety of grape seed [Muscat] extract. . . . It is suggested that applicant demonstrate, via a side-by-side comparison, the results obtained when using the grape seed extract of the cited reference and those results obtained by utilizing the claimed Muscat grape seed extract."

Accordingly, Applicants did ultimately perform side-by-side comparisons with the closest cited prior art (Perkes), as suggested by the Examiner. In a Response dated April 7, 2006, Applicants submitted a Declaration by Erin Stone, an employee of the Assignee of the present application, as evidence in support of the unexpected results, which showed that compositions containing a Muscat grape seed extract exhibited surprisingly high reductions in platelet aggregation activity when evaluated in a side-to-side experiment to compositions

containing other varieties of grape seed extracts. Because Federal Circuit precedent requires that surprising results be evaluated based on a comparison with the results achieved by the closest prior art, the formulations were made to track closely the formulations in the closest prior art (Perkes), with some slight modifications. As shown in that Declaration, compositions containing a Muscat grape seed extract demonstrated significant increases in platelet aggregation inhibition activity in two different supplement formulations (*i.e.*, 83.47% ± 2.1% (in Formulation A at a dose of 380 mg/L) and 77.8% ± 0% (in Formulation B at a dose of 250 mg/L)) as compared to identical compositions containing one or the other of two grape seed extracts, grape seed extract 1 (grape seed extract of mixture of ruby red, chardonnay, colombard, and chenin blanc grapes) and grape seed extract 2 (grape seed extract of champagne grapes). *See* Tables I and II of the Stone Declaration.

The Declaration set forth standard deviations as well as p values, allowing an evaluation of the statistical significance of the results. Applicants note that Formulation A made with the Muscat grape seed extract at a dose of 380 mg/L demonstrated a statistically significant increase in the platelet aggregation inhibition activity as compared to Formulation A made with grape seed extract 1 ($p=0.002$) and as compared to Formulation A made with grape seed extract 2 ($p=0.02$) (both at the same 380 mg/L dose). In addition, Formulation B made with the Muscat grape seed extract at a dose of 250 mg/L demonstrated a statistically significant increase in the platelet aggregation inhibition activity as compared to Formulation B made with grape seed extract 1 ($p=0.001$) or Formulation B made with grape seed extract 2 ($p=0.035$) (both at the same 250 mg/L dose). Applicants note that Formulation A at the higher 760 mg/L dose yielded very high inhibition results for all seed extracts (all 100%), indicating that this dosage was not a meaningful dosage at which to perform the assay for comparison purposes. Applicants also note that Formulation B at the lower 125 mg/L dose yielded very low inhibition results for all seed extracts (ranging from -18.6 to 3.5%), indicating that this dosage was also not a meaningful dosage at which to perform the assay for comparison purposes. Thus, for the relevant dosages in this assay where a meaningful comparison of the results obtained with Muscat grape seed extract as compared to other grape seed extracts can be obtained, the formulations that included Muscat grape seed extract all demonstrated statistically significant increases in platelet aggregation inhibition as compared to the closest prior art formulations containing other grape seed extracts.

Accordingly, Applicants respectfully assert that the prior evidence of record establishes that the claims are not obvious given Perkes in view of Shrikhande.

Applicants also refer the panel to the holding in *In re Soni,* in which the Federal Circuit stated: "when an applicant demonstrates *substantially* improved results, as Soni did here, and *states* that the results were unexpected, this should suffice to establish unexpected results *in the absence of* evidence to the contrary." *In re Soni*, 54 F.3d 746, 751 (Fed. Cir. 1995) (emphasis in the original). Applicants submit that the data discussed above demonstrate the substantially improved properties of the claimed compositions containing Muscat grape seed extracts. The Declaration states that the Muscat grape seed formulations exhibit statistically significant increase in platelet aggregation inhibition as compared to grape seed extracts 1 and 2. The Office has not set forth any evidence to rebut these unexpected results. Accordingly, Applicants respectfully assert that the claims are not obvious and request that the panel withdraw the rejections under 35 U.S.C. § 103.

Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 6/18/07

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